

REMARKS

Claims 7-19, 21, 25, 26, and 28-43 are pending in the present application.

The rejection of Claims 7-13, 15-19 and 21 under 35 U.S.C. 102(b) over Smith, Jr., U.S. Patent No. 5,399,343, is obviated by amendment.

Applicants make no statement with respect to the propriety of the Examiner rejection of Claims 7-13, 15-19 and 21 and in no way acquiesce to the same. Accordingly, Applicants request that the withdrawal of composition claims be without prejudice toward their presentation in an ensuing continuation application.

Claim 7 has been amended to include the limitations of previously pending Claim 27 and, independently, Claim 28. As such, Applicants note that the presently pending claims are drawn to dental treatment methods. Applicants wish to acknowledge the Examiner's recognition that Smith, Jr. fails to disclose or suggest these methods.

In view of the amendments herein, Applicants submit that Smith, Jr. does not anticipate the claimed invention. Withdrawal of this ground of rejection is requested.

The rejection of Claims 7-19, 21, and 25-28 under 35 U.S.C. §103(a) over Imazato et al is obviated in part by amendment and traversed in part.

At the outset, Applicants wish to note that Claims 7-19, 21, 25, and 26 have been amended such that the scope of the present invention is defined by method claims corresponding to previously pending Claims 27 and 28.

Imazato et al is cited as allegedly disclosing an antimicrobial dental composition. However, as the Examiner recognizes, the disclosure of Imazato et al fails to disclose or suggest the presence of a base, such as sodium, in the dental composition. The Examiner

attempts to discount this deficiency by alleging, "it is well known to provide compositions that have suitable pHs to biological environment." (page 4, lines 15-17 of the Office Action mailed August 10, 2005). The Examiner offers no evidence of record to support such a conclusion. The Examiner is reminded that MPEP §2144.03 states:

It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known... It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.").

Moreover, Applicants disagree with this allegation by the Examiner. In fact, Applicants submit that in the field of dentifrices, environmental pH adaptation is generally not considered to be critically important. In other words, a pH regulator is not generally added for the purpose of adaptation to biological environment.

Further, MPEP §2142 states: "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation... to modify the reference... Second, there must be a reasonable expectation of success. Finally, the prior art reference... must teach or suggest all the claim limitations." In this case, not only has the Examiner failed to properly support the alleged "obvious" addition of the claimed basic component, the Examiner has also failed to provide any explanation of how the art would meet the aforementioned criteria to support even a *prima facie* case of obviousness.

Applicants note that a critical feature of the present invention as claimed in pending Claims 7 and 28 is that the antibacterial composition contains the specific basic compound (e). As set forth in the specification on page 16, lines 21-25, the addition of the basic compound

(e) to an antibacterial composition containing components (a), (b), (c), and (d) remarkably improves the storage stability and antibacteriability of the composition.

The remarkable improvement flowing from the inclusion of the basic component (e) is demonstrated in Table 2 (page 38) of the present specification. For the Examiner's convenience, Table 2 is reproduced below in relevant part:

Table 2

		Blend Ratio (wt. %)				
		Example 6	Example 7	Example 8	Example 9	Comp. Ex. 8
Antibacterial Composition	MDPB	3	3	3	3	3
	MDP	10	10	10	10	10
	HEMA	43.5	43.5	43.5	43.5	43.5
	Distilled water	43.5	43.5	43.5	43.5	43.5
	TMDPO	0.1	0.1	0.1	0.1	0.1
	TEA	2	-	-	-	-
	NaHCO ₃	-	2	-	-	-
	LiOH	-	-	2	-	-
	H ₂ KPO ₄	-	-	-	2	-
(1) Antibacterial Property (Cell Death Percentage: %)						
Concentration	20%	100	100	100	100	100
	10%	100	100	100	100	91
	5%	100	100	100	100	68
	2%	82	91	90	88	48
	1%	66	70	72	68	12
(2) Adhesiveness (MPa)						
	Bovine enamel	15.8	15.9	15.6	15.1	18.1
	Bovine dentin	14.6	15.0	15.1	15.2	15.6
(3) Storage Stability (at 50°C for 1 month)						
Discoloration	ΔL^*	0.4	0.3	0.5	0.5	0.4
	Δb^*	0.8	0.9	1.0	0.8	1.0
	Visual check	colorless	colorless	colorless	colorless	colorless
Adhesiveness	Bovine dentin	14.1	14.4	14.3	14.2	6.9

Examples 6-9 in Table 2 correspond to the method of the present invention wherein one of triethanolamine (TEA), NaHCO_3 , LiOH , and H_2KPO_4 are used, respectively. Comparative Example 8 corresponds to the method of Imazato et al wherein a basic compound defined by (e) is omitted.

As evidenced by Table 2, the antibacterial compositions comprising MDPB, MDP, HEMA, distilled water, TMDPO, and any of an aliphatic amine, an alkali metal hydroxide or a strong basic acid salt (Examples 6 to 9) completely killed the cells of *Streptococcus mutans* even when the amount of MDPB therein was about 3% by weight of the composition and the concentration of the composition was 5%. In addition, the adhesiveness of these antibacterial compositions was good; and even after stored in a thermostat at 50°C for 1 month, the compositions did not discolor when observed visually, and their bonding strength to dentin lowered only slightly.

In contrast, when the same composition was prepared with the exception of the basic compound (see Comparative Example 8, i.e., Imazato et al), the antibacterial composition could not completely kill the cells of *Streptococcus mutans* even when its concentration was 10%. In addition, when stored in a thermostat at 50°C for 1 month, the bonding strength of the composition to dentin was significantly reduced. Such a result is neither disclosed nor suggested by Imazato et al.

In summary, Applicants submit that Imazato et al does not offer any suggestion or motivation to modify its disclosure to include a specific basic component as defined in (e) of the present claims. Further, the Office fails to meet its burden of establishing a general motivation to add any basic component to the composition disclosed by Imazato et al, much less the specifically claimed basic components defined in (e) of the present claims. Further, Imazato et al fails to provide a reasonable expectation of the results flowing from the claimed

invention as evidence by Table 2 (above). And, finally, as recognized by the Examiner, Imazato et al fails to teach or suggest all the claim limitations, namely the specific basic component as defined in (e) of the present claims.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

Finally, on page 2 of the Office Action mailed August 10, 2005, the Examiner states that Claim 7 was not amended in the response filed on May 20, 2005, and that the proper status identifier should be "previously presented" not "currently amended." Applicants submit that this indication by the Examiner is in error as Claim 7 was, in fact, amended in the response filed on May 20, 2005. Specifically, Claim 7 was amended to insert a semicolon on line 8 of the claim after the term "tertiary aliphatic amine." Applicants raise this issue to ensure that the Office's official claims accurately reflect the amendments of record.

Applicants submit that the present application is now in condition for allowance.
Early notice to this effect is earnestly solicited.

Respectfully submitted,

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